K123575

FEB 19 2013

Section 5: 510(k) Summary

MammoWorkstation

510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date:	13 November 2012
Submitter:	GE Healthcare, (Image Diagnost International GmbH) Oskar-Schlemmer-Str. 11; 80807 München, Germany
Primary Contact Person:	Mounir Zaouali, RAC Regulatory Affairs Leader GE Healthcare, (GE Medical Systems, SCS) 283 RUE DE LA MINIERE 78530 BUC – FRANCE Phone : + 33 1 30 70 45 39 Fax : + 33 1 30 70 41 40 Mounir.Zaouali@ge.com
Secondary Contact Person:	Steven Kachelmeyer, RAC Regulatory Affairs Director - X-ray GE Healthcare Phone: 262-548-2432 Fax: 262-997-1080 Steven.Kachelmeyer@med.ge.com
Device Trade Name:	MammoWorkstation
Common/Usual Name:	Medical imaging software
Classification Names: Product Code:	Picture archiving and communication system Class II CFR 892.2050 System, Image Processing, Radiological, LLZ
Predicate Device(s):	MammoWorkstation (version 3.3.2) K081630 Hologic SecurView DX K103385

Device Description:	The MammoWorkstation is a medical image review workstation software for diagnostic and screening mammography. Mammoworkstation has the capability to review Digital Breast Tomosynthesis (DBT) images that are compatible with DICOM Breast Tomosynthesis Image Storage. It is a software product.
Intended Use:	MammoWorkstation is designed to assist radiologists in conducting primary diagnostic review for diagnostic and screening mammography through flexible and interactive manipulation of multi-modality softcopy images. It provides image review, manipulation, analysis, post-processing and printing capabilities that support image management display needs in the medical environment. MammoWorkstation is designed to give easy and economic access to and display of multi-modality softcopy images, structured reports, and CAD results through interfaces to various image storage devices using DICOM or similar interface standards. It supports creation of structured reports according to the DICOM breast imaging report templates. MammoWorkstation supports teleradiology and teleconferencing providing access to multi-modality softcopy images and structured reports in multiple locations within and outside the hospital. Lossy compressed mammographic images must not be used for primary diagnostic interpretation unless approved for use in digital mammography. Display monitors used for primary diagnostic interpretation of mammographic images must be approved for use in digital mammography."

	All images sent to or imported in the Mammoworkstation must conform to regulatory requirements. Image quality must conform with applicable quality guidelines. All modalities must be certified for soft-copy reading.
Technology:	MammoWorkstation is software product. It is designed to run on a standard workstation with a minimum of three monitors, one control monitor and high-resolution monitor (s) that are cleared for mammography. review It runs on Windows Operating System.
Determination of Substantial Equivalence:	Summary of Non-Clinical Tests: The MammoWorkstation and its applications comply with voluntary standards as detailed in Section 9, 11 and 17 of this premarket submission. The following quality assurance measures were applied to the development of the system: Risk Analysis Requirements Reviews Design Reviews Testing on unit level (Module verification) Integration testing (System verification) Performance testing (Verification) Safety testing (Verification) Simulated use testing (Validation) Summary of Clinical Tests: The subject of this premarket submission, MammoWorkstation, did not require clinical studies to support substantial equivalence.
Conclusion:	GE Healthcare considers the MammoWorkstation to be as safe, as effective, and performance is substantially equivalent to the predicate device(s).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 19, 2013

Image Diagnost International GmbH
c/o Mounir Zaouali
GE Healthcare, (GE Medical Systems, SCS)
283 RUE DE LA MINIERE
BUC
FRANCE 78530

Re: K123575
Trade/Device Name: MammoWorkstation
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: November 15, 2012
Received: November 20, 2012

Dear Mr. Zaouali:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

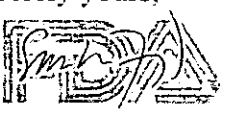
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K123575

Device Name: MammoWorkstation

Indications For Use:

MammoWorkstation is designed to assist radiologists in conducting primary diagnostic review for diagnostic and screening mammography through flexible and interactive manipulation of multi-modality softcopy images.

It provides image review, manipulation, analysis, post-processing and printing capabilities that support image management display needs in the medical environment.

MammoWorkstation is designed to give easy and economic access to and display of multi-modality softcopy images, structured reports, and CAD results through interfaces to various image storage devices using DICOM or similar interface standards. It supports creation of structured reports according to the DICOM breast imaging report templates.

MammoWorkstation supports teleradiology and teleconferencing providing access to multi-modality softcopy images and structured reports in multiple locations within and outside the hospital.
Lossy compressed mammographic images must not be used for primary diagnostic interpretation unless approved for use in digital mammography.

Display monitors used for primary diagnostic interpretation of mammographic images must be approved for use in digital mammography.

All images sent to or imported in the Mammoworkstation must conform to regulatory requirements. Image quality must conform with applicable quality guidelines. All modalities must be certified for soft-copy reading.

Prescription Use_X___ AND/OR Over-The-Counter Use_ _
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

510(k) K123575